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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,082

05/15/2007

Kanji Ohyama

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,082	Applicant(s) OHYAMA, KANJI	
	Examiner Elizabeth F. McElwain	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/22/06.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed June 22, 2006 has been entered.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 18-23 and 25, drawn to an isolated gene encoding a delta-6 fatty acid desaturase.

Group II, claim(s) 5-8, drawn to an isolated gene encoding a delta-6 chain elongating enzyme.

Group III, claim(s) 9-12, drawn to an isolated gene encoding a delta-5 desaturase.

Group IV, claim(s) 13, 14 and 27, drawn to a delta-6 desaturase protein and method of using.

Group V, claim(s) 15, drawn to a protein that has delta-6 chain elongating activity.

Group VI, claim(s) 16, drawn to a delta-5 desaturase protein.

Group VII, claim(s) 17, drawn to an isolated antibody which recognized a delta-6 desaturase protein of claim 13.

Group VIII, claim(s) 24, drawn to a composition comprising at least one fatty acid listed in the claim.

Group IX, claim(s) 26, drawn to a gene detecting instrument comprising at least a portion of a nucleotide sequence or complementary sequence of a gene of claim 1.

Group X, claim(s) 28, drawn to a gene or substance obtained by a screening method of claim 27.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: The invention of Group I requires an isolated *Marchantiales*-derived gene that encodes a protein having a delta-6 fatty acid desaturating activity. However, each of the inventions of Groups II, III, V, VI, VIII are drawn to distinct products that do not require a delta-6 fatty acid desaturase coding sequence.

3. In addition, the nucleic acid of Group I does not share a special technical feature with the polypeptide of Group IV. According to the PCT Administrative Instructions, for molecules to be of similar nature, they need to share a common core structure and a common property or activity. Nor does the relationship of the polypeptides of Group IV and the polynucleotides of Group I conform with Example 17 of the PCT Administrative Instructions. The instant claims are not directed to a single molecule, but encompass a family of molecules which are defined by a minimal structure. For these reasons, there is no shared technical feature between the nucleic acids of Group I and the polypeptides of Group IV.

4. The polypeptide of group IV and the antibody of group VII are patentably distinct for the following reasons:

While the inventions of both group IV and group VII are polypeptides, in this instance the polypeptide of group IV is a single chain molecule that functions as an enzyme, whereas the polypeptide of group VII encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group IV and the antibody of group VII are structurally distinct molecules; any relationship between a polypeptide of group IV and an antibody of group VII is

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dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group IV is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group VII is defined in terms of its binding specificity to a small structure within SEQ ID NO: 2. Thus immunization with the polypeptides of group II would result in the production of antibodies outside the scope of group VII. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group IV and group VII would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group VII. Furthermore, antibodies which bind to an epitope of a polypeptide of group IV may be known even if a polypeptide of group IV is novel. In addition, the technical literature search for the polypeptide of group IV and the antibody of group VII are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Therefore, the antibodies of Group VII also do not share a special technical feature with the nucleic acids of Group I.

5. Also, the inventions of Groups VIII-IX fail to share a corresponding technical feature with the nucleic acids of Group I, wherein the composition comprising a fatty acid of Group VIII does not require the nucleic acid of Group I, and the part of the nucleic acid required by Groups IX-X does not require the nucleic acid of Group I that encodes a delta-6 desaturase, and would

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require additional search and examination. In addition, each of the products of Groups I-IX and X are distinct products that fail to share a corresponding technical feature.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the requirement for different searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638